1. Purpose

   1.1. This procedure establishes a standard system for documenting and maintaining discipline specific methods of analysis.

   1.2. Validation of new or revised methods of analysis assesses the ability of a procedure to reliably obtain accurate results, to determine the conditions under which such results can be obtained and to determine the limitations of the procedure.

2. Scope

   2.1. This procedure is applicable to all Laboratory Services laboratories

3. References

   ATF-LS-4.3 Document control

   ATF-LS-4.13 Control of records

4. Policy

   4.1. Methods of analysis will be established and maintained for all types of analyses performed in ATF Laboratories. Methods will be maintained according to ATF-LS-4.3 Document control. Method validation records will be maintained according to ATF-LS-4.13 Control of records.

5. Validation of methods

   5.1. Any new or revised procedure used in the analysis of evidence submitted to ATF laboratories will be validated using the guidelines outlined in this procedure.

   5.2. Prior to implementing a procedure that has been validated in another laboratory, the laboratory will conduct its own internal validation tests using known samples, unknown samples and other samples as appropriate to the method. Validation tests may be conducted collaboratively with other laboratories

   5.3. New procedures shall not be used on case samples until satisfactory performance is demonstrated with control samples.

   5.4. New procedures will be written in an acceptable format, maintained in the Methods Manual, and distributed to all appropriate sections.

6. Procedure

6.1. Format

6.1.1. Formatting may vary from discipline to discipline, however all methods of analysis should include the following where appropriate to the method.

I. Scope

This section designates the analysis to which the method is applied.

II. References

This section should include standard approaches, validation studies, original scientific papers and published standards used in the method described.

III. Apparatus/ reagents

Instrument maintenance and calibration procedures, reagent/ standard solutions and reference standards used in analysis are maintained in discipline procedure/ methods manuals. Each discipline specific method manual must detail the requirements for instrument/equipment maintenance and calibration for all instruments, equipment and measuring devices used in casework. Where appropriate to what is being reported, methods documents should reference the procedures used for ensuring traceability of standards and measuring devices. Logbooks documenting performance of required maintenance and calibration will be maintained in the section responsible for the instrument.

IV. Safety precautions

This section shall address safeguards, including goggles, gloves, hoods, and other personal protective equipment required for analysis.

V. Procedures

Procedures may include:

- sample preparation methods
- controls
- use of operating parameter sheet
- allowance for variation for non-routine examinations

VI. Quality assurance or controls

This section shall address possible sources of error, control charts and reference standards regularly used in analysis.

6.2. Implementation of methods of analysis

6.2.1. New methods or suggestions for revision of current methods will be reviewed and approved in Qualtrax.

6.2.1.1. Validation records must be maintained along with reference materials as documentation of the method validation

6.3. Revisions/ changes/ new

6.3.1. Requests for changes to existing documents as well as recommendations for establishment of new documents may be made by any Laboratory Services employee. Requests will be made through the requestor's immediate supervisor.

6.3.2. The proposed method will be reviewed in Qualtrax and following review, approved by the Technical Leader.

6.4. Validation of methods

6.4.1. Validation considerations for all discipline methodologies

6.4.1.1. Validation of new technical procedures must be approved by the appropriate Technical Leader. Validation of a new procedure may be done by an outside laboratory developing the procedure or internally.

6.4.1.2. To be considered for approval, a written procedure accompanied by a validation study must be provided to the appropriate Technical Leader.

6.4.1.3. The validation study must demonstrate the reliability of the procedure in-house. This internal validation must include the following:

- The procedure must be tested using known samples.
- If the procedure is a modification, which materially effects the results of an analysis, the modified procedure must be compared to the original using identical samples.
- The laboratory must determine the precision of the procedure and identify any possible sources of error (if applicable).
- If a significant modification to an existing procedure is made, the modified procedure will be compared with the original procedure to verify the accuracy and reliability of the results. Where appropriate, examiners using the modified procedure will analyze unknown samples.
- Literature references used in method validation will be documented and included with validation records.

6.4.1.4. Records of validation will be maintained.

6.4.2. Biology methodology

6.4.2.1. In addition to the above mentioned requirements, biology methodology must undergo the following additional validation studies.

6.4.2.1.1. Novel methodologies must undergo developmental validation that addresses the following if applicable:

- accuracy
- precision
- reproducibility
- characterization of each locus
- species specificity
- sensitivity
- stability
- mixtures
- population databases
- population database tests for independence
- population database information including allele and frequency distributions

6.4.2.1.2. Methodologies that have been developmentally validated by another laboratory must undergo an internal validation which addresses the following if applicable:

- known and non-probative samples
- reproducibility
- precision
- match criteria
- sensitivity and stochastic effects
- mixtures
- contamination
- qualifying test

7. Controls

7.1. Quality Programs

7.1.1. Quality Programs will coordinate reviews of all methods documents at least once annually. The annual reviews will be documented in Qualtrax. A review of records of validation created during the review period will be made during the annual internal review.

7.2. All employees

7.2.1. All employees are responsible for identifying any method document that may contain inconsistencies, are not working, or require change based on another change in how business is done.